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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,911	10/16/2003	Anthony E. Winston	51000	7470

7590 11/29/2005

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,911	WINSTON ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (UPS 6,248,310 or 6,214,321).

USP 6,248,310 discloses remineralizing compositions comprising two part dentifrices (pastes or gels: see col. 4, lines 11-16) in which the first phase contains a partially water soluble calcium salt such as calcium sulfate in an amount ranging from 0.1 to 30 percent by weight (col. 3, lines 25-50), and the second phase contains both 1) a bicarbonate in an amount ranging from 0.1 to 60 percent by weight (col. 3, lines 55-65) and 2) a fluoride salt in an amount ranging from 0.01 to 5 percent by weight (see the passage bridging col. 3, line 66 to col. 4, line 10). The second phase may also contain a water-soluble carbonate salt such as sodium carbonate (col. 3, line 60); the relative proportions of sodium carbonate to calcium salt used fall within the ratios recited by instant claim 13, as is clear from working example 3 at col. 7.

USP 6,214,321 is cumulative of USP 6,248,310. Both teach that the first phase has a pH of less than 7 (i.e., is acidic), and the second phase a pH of greater than 7 (i.e., is basic); see col. 3, lines 50-57 of the '310 reference, and col. 3, lines 34-41 of the

'321 reference. Neither prior art reference explicitly states that a solution formed by mixing the first and second parts with water and/or saliva has a pH of between 7.0 and 10.0, as required instantly. It is the examiner's position that one skilled in the art would reasonably expect this to occur inherently, however, given that mixing an acidic composition with a basic composition in equal amounts as done here will inevitably produce a substantially neutral (pH 7) composition.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-6 and 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321), each primary reference being considered individually and separately and each being taken further in view of Gaffar et al (USP 4,177,258).

USP 6,248,310 discloses remineralizing compositions comprising two part dentifrices (pastes or gels: see col. 4, lines 11-16) in which the first phase contains a partially water soluble calcium salt such as calcium sulfate in an amount ranging from 0.1 to 30 percent by weight (col. 3, lines 25-50), and the second phase contains both 1) a bicarbonate in an amount ranging from 0.1 to 60 percent by weight (col. 3, lines 55-65) and 2) a fluoride salt in an amount ranging from 0.01 to 5 percent by weight (see the passage bridging col. 3, line 66 to col. 4, line 10). The second phase may also contain a water-soluble carbonate salt such as sodium carbonate (col. 3, line 60); the relative proportions of sodium carbonate to calcium salt used fall within the ratios recited by instant claim 13, as is clear from working example 3 at col. 7.

USP 6,214,321 is cumulative of USP 6,248,310. Both teach that the first phase has a pH of less than 7, and the second phase a pH of greater than 7; see col. 3, lines 50-57 of the '310 reference, and col. 3, lines 34-41 of the '321 reference. In the interest of completeness of prosecution, purely *arguendo* and for the purposes of this particular ground of rejection only, it will be assumed that the prior art does not *per se* disclose compositions which when mixed are neutral.

The secondary reference teaches that the optimum pH for remineralizing dentifrices lies between 5 and 9, and particularly 6.8 and 7.5, which approximates normal physiological conditions for effecting remineralization. See col. 2, lines 26-42. Since the secondary reference is cited as a general teaching reference, it does not disclose the instantly claimed two phase calcium/bicarbonate remineralizing compositions.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Similarly, the determination of optimal values within a disclosed range is generally considered obvious. In re Boesch, 205 USPQ 215 (CCPA 1980). See also In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (That court reaffirming the previous Aller and Boesch decisions, stating at page 1330 that: "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a set of disclosed percentage ranges is the optimum combination of percentages.") Accordingly, it would have been obvious to

have adjusted the relative pH's of the first and second phases of the compositions of either primary reference to provide a final, mixed composition for application to the teeth having a pH of 6.8 to 7.5, motivated by the desire to provide optimum remineralization effectiveness as taught by the secondary reference, and consonant with the reasoning of the cited precedent.

2) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321), each primary reference being taken individually and separately and each further in view of Winston et al (USP 6,159,449).

The primary references are discussed in the "Anticipation" rejection supra, and each differs from the instant claims insofar as they do not specifically include a water soluble orthophosphate salt in the second dentifrice phase.

The secondary reference teaches that it is known to add water soluble orthophosphate salts to the fluoride-containing phase of a two-phase remineralizing dentifrice in order to optimize effectiveness by matching the orthophosphate levels present in naturally occurring saliva. See col. 14, lines 27-50. The secondary reference differs from the instant claims insofar as it does not disclose two phase compositions having the particular combination of components claimed instantly.

It would have been obvious have incorporated a water-soluble orthophosphate salt into the second phase of the remineralizing dentifrices of either of the primary references, motivated by the desire to provide optimum effectiveness as taught by the secondary reference.

3) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321), each primary reference being considered individually and separately and each being taken further in view of Winston et al (USP 6,159,449), and each combination of primary and secondary references being taken further in view of Gaffar et al (USP 4,177,258).

The primary and secondary references, and the rationale for combining their teachings, is set forth above. Again, assuming the primary references do not specifically disclose compositions which are neutral upon mixing, it would then have been obvious to have adjusted the relative pH's of the compositions suggested by the combined teachings of the primary and secondary references to provide same, motivated by the desire to optimize effectiveness as taught by the tertiary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614